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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,292	05/31/2007	Chawnshang Chang	24376.18.8402	1600

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PATENT CORRESPONDENCE  
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EXAMINER
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HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1643

NOTIFICATION DATE	DELIVERY MODE
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09/03/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

agg.patent.docketing@agg.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/582,292	<b>Applicant(s)</b> CHANG, CHAWNSHANG	
	<b>Examiner</b> Alana M. Harris, Ph.D.	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) 6-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I (claims 1-5) in the reply filed on August 5, 2009 is acknowledged. The traversal is on the ground(s) that "[a]t best, Fujimoto...indicated that androgen receptor is expressed in certain breast cancers" and Applicants reference confusion regarding the Monifar reference, see Remarks, bridging paragraph of pages 4 and 5. This is not found persuasive because both references teach the two active steps listed in claim 1, a. obtaining a tissue sample and b. assaying for the presence of androgen receptor. Hence, the Requirement is maintained and sustained for the clear and distinct reasons listed herein and in the Requirement mailed June 5, 2009

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-52 are pending.

Claims 6-52, drawn to non-elected inventions is withdrawn from examination.

Claims 1-5 are examined on the merits.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Thompson/ U.S. Patent number 7,029,859 B2 (filed March 5, 2001). Thompson discloses Example 2, wherein both rodent and human model systems are assessed, see columns 22 and 23. Tissues from male subjects were analyzed for androgen levels (AR) using a monoclonal antibody, see lines 51-65; paragraph bridging columns 22 and 23; and Figure 2.

5. Claims 1, 2, 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Fujimoto et al. (Laboratory Investigation 80(9): 1465-1471, September 2000) discloses assaying extramammary paget's disease (EMPD) surgical specimens (including from males) for the presence of AR with an antihuman AR monoclonal antibody, see page 1469, Materials and Methods section.

6. Claims 1, 2 and 4 are rejected under 35 U.S.C. 102(a) as being anticipated by Moinfar et al. (Cancer 98(4): 703-711, August 15, 2003) discloses immunohistochemical assays for AR in samples of breast carcinomas with antibodies, see page 704, Materials and Methods section.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujimoto et al. (Laboratory Investigation 80(9): 1465-1471, September 2000), and further in view of Thompson/ U.S. Patent number 7,029,859 B2 (filed March 5, 2001). The teachings of Fujimoto have been presented in the 102(b) rejection. Fujimoto does not teach the claimed method, wherein the subject is a mouse.

However, Thompson teaches both, rodent and human model systems can be assayed for androgen receptor (AR) levels using a monoclonal antibody, see lines 51-65; paragraph bridging columns 22 and 23; and Figure 2. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to implement the teachings of Thompson in the method of Fujimoto. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of all the references that assessing AR levels can be conducted easily and the presence or absence of the said levels are predictive of disease conditions.

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9. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moinfar et al. (Cancer 98(4): 703-711, August 15, 2003), and further in view of Thompson/ U.S. Patent number 7,029,859 B2 (filed March 5, 2001). The teachings of Fujimoto have been presented in the 102(b) rejection. Moinfar does not teach the claimed method, wherein the subject is a mouse and male.

However, Thompson teaches both, male rodent and human model systems can be assayed for androgen receptor (AR) levels using a monoclonal antibody, see lines 51-65; paragraph bridging columns 22 and 23; and Figure 2. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to implement the teachings of Thompson in the method of Moinfar. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of all the references that assessing AR levels can be conducted easily and the presence or absence of the said levels are predictive of disease conditions.

***Conclusion***

10. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached Monday through Saturday, 7:30 am to 6:30 pm.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.  
30 August 2009

/Alana M. Harris, Ph.D./  
Primary Examiner, Art Unit 1643